

ENVIRONMENTAL PROTECTION AGENCY FY 2017 INTEGRITY ACT REPORT

Current Weaknesses and Significant Deficiencies ORD

This is an existing			
<input type="checkbox"/> Material Weakness	<input checked="" type="checkbox"/> Agency Weakness	<input type="checkbox"/> Significant Deficiency	<input type="checkbox"/> Office Weakness
For FY 2017, it			
<input type="checkbox"/> Has been corrected	<input checked="" type="checkbox"/> Will carry over	<input type="checkbox"/> Has been downgraded	

1. **Title of Issue:** Strengthening EPA’s Process for Developing Chemical Assessments Under IRIS

Planned Closure Date: 2019 for activities ORD has the lead on. This GAO risk finding also pertains to TSCA-related activities in OCSPP/OPPT.

2. **Executive Summary:** Over the last several years, ORD implemented numerous actions to enable the IRIS Program to produce timely, transparent, and credible assessments in support of EPA’s mission to protect public health and the environment. In 2017, the Government Accountability Office (GAO) acknowledged that, based on actions taken in ORD’s Integrated Risk Information System (IRIS) Program, EPA progressed from: “not met” to “partially met” on two criteria—capacity and demonstrated progress; “partially met” to “met” for monitoring; and continued to partially meet the criterion for having an action plan. IRIS continues to meet the leadership commitment criterion. Discussions continue with the GAO on further steps and progress to remove the IRIS Program from GAO’s High Risk List, including planning a face-to-face meeting in summer 2017 to evaluate incremental progress toward resolution of open recommendations. While progress on recommendations will be recorded and updated on the GAO website, the next opportunity to be removed from the list is early calendar year 2019, when GAO will issue their next biennial High Risk Report.

Corrective Actions Taken to Date:

The Agency continues to make progress in addressing GAO concerns. Corrective Actions the agency has taken include:

- In January 2017, EPA appointed new leadership to the National Center for Environmental Assessment and to its IRIS Program.
- In February 2017, NCEA began to build a more proactive pipeline to provide the significant support required for TSCA implementation under EPA’s Office of Pollution Prevention and Toxics (OPPT).
- In February 2017, launched a pilot effort structured as case studies of accelerated systematic review methodologies/protocols and related automation tools. For this pilot, several existing assessments are being updated to meet focused high-priorities for EPA program and regional offices.
- A critical hire in FY2017 was the Assistant Center Director for Scientific Support

dedicated to engaging EPA program and regional offices and states, with the goal to improve NCEA's ability to be responsive to dynamic needs.

- In FY2017, NCEA deployed program and project management (PM) for the IRIS Program. This includes working with chemical managers to develop timelines and a system that tracks the array of IRIS products in development, allowing the IRIS Program to more effectively and efficiently utilize human resources across assessment projects and ensure timely delivery of products. NCEA has developed tools for tracking decisions and actions taken, and has ongoing training for staff and managers in the use of project management (PM) tools and systems.

ORD made significant improvement in the ratings of the IRIS Program in GAO's most recent High Risk Report, released in February 2017 (See Table 1). The 2017 report continued GAO's use of five criteria to help programs gauge their progress in resolving their high risk designation (started in the 2015 report).

Table 1. Summary of 2015 and 2017 GAO High Risk Criteria Ratings (rating component specific to the IRIS Program).

GAO High Risk Criteria	2015 Rating	2017 Rating
Leadership Commitment	Met	Met
Monitoring	Partially Met	Met
Action Plan	Partially Met	Partially Met
Demonstrated Progress	Not Met	Partially Met
Capacity	Not Met	Partially Met

Although the IRIS Program remains on the High Risk List in the 2017 report, the program improved in the high risk criteria, meeting two of the five criteria (Leadership Commitment and Monitoring), as well as improving the rankings in Demonstrated Progress and Capacity.

Remaining Corrective Actions:

Additionally, ORD has been engaged in continual, ongoing discussion with GAO regarding the recommendations from the 2008, 2012, and 2013 reports. Of the seventeen recommendations issued in these three reports, as of March 2017, ORD has successfully closed ten recommendations and is rapidly moving to address the remaining seven (See Table 2).

Table 2. Update on Open GAO Recommendations (as of April 2017)

CHEMICAL ASSESSMENTS: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System

GAO-08-440: Published: Mar 7, 2008. Publicly Released: Apr 29, 2008.

Recommendation	Comments
(5. Recommendation: To develop timely chemical w/ Risk information that EPA needs to effectively conduct its mission, the Administrator, EPA, Publicly Rel	<p>Status: Open</p> <p>Priority recommendation</p> <p>Comments: In October 2016 we reviewed information</p>

<p>should require the Office of Research and Development to reevaluate its draft proposed changes to the IRIS assessment process in light of the issues raised in this report and ensure that any revised process periodically assesses the level of resources that should be dedicated to this significant program to meet user needs and maintain a viable IRIS database.</p> <p><i>CHEMICAL ASSESSMENTS: Challenges Remain with Program</i> GAO-12-42: Published: Dec 9, 2011. Publicly Released: Dec 9, 2011.</p>	<p>Status: Open</p> <p>Priority recommendation</p> <p>Comments: In October 2016 we reviewed information provided by EPA related to this recommendation. The issuance of the Integrated Risk Information System (IRIS) Program Multi-Year Agenda in December 2015 demonstrated progress in responding to this recommendation. While we are currently reviewing additional documentation on how the agenda development process assessed the level of resources needed to meet user demand and to maintain a viable IRIS database, we will reevaluate how EPA continues to document the level of resources dedicated to this program to determine whether updates are occurring periodically.</p> <p>April 2017 Update: As indicated in the preamble, in addition to the Multi-Year Agenda, we will ground-truth program and regional office priority needs annually, evaluate the continued responsiveness of the Agenda for that fiscal year, and realign resources and priorities as needed. We started this ground-truthing informally in 2017, and depending on feedback from the offices and the SAB-CAAC, we will formalize this process starting in 2018.</p>
Recommendation	Comment
<p>1. Recommendation: To better ensure the credibility of IRIS assessments by enhancing their timeliness and certainty, the EPA Administrator should require the Office of Research and Development to assess the feasibility and appropriateness of the established time frames for each step in the IRIS assessment process and determine whether different time frames should be established, based on complexity or other criteria, for different types of IRIS assessments.</p>	<p>Status: Open</p> <p>Priority recommendation</p> <p>Comments: In October 2016 we reviewed information provided by EPA related to this recommendation. While in July 2013, the EPA issued "enhancements" to the IRIS process and throughout 2016, EPA provided us with details on its online chemical information. EPA stated that the Program introduced the idea that different timelines are needed for different types of assessments based on criteria such as complexity (i.e., large database, many endpoints, complex questions about dose-response, multiple science issues, and</p>

	<p>novel approaches), potential public health impact, and the amount of new research that needs to be considered.</p> <p>Consequently, two sets of timelines for the IRIS assessment process were developed, one set for "standard" assessments and one set for "complex" assessments. GAO believes that this is important progress but that EPA needs to continue to determine whether different time frames should be established.</p> <p>April 2017 Update: In 2017, we furthered this concept. NCEA assessments that support policy and regulatory decisions are being consolidated into a 'portfolio' of <i>Chemical Evaluation</i> products that optimize the application of best available science and technology. The workflow will be reoriented and timelines and resources will be tailored to flexibly fit the intended purpose of the assessment as described in the Assessment Plan (see preamble). Examples of other products incorporated in the portfolio may derive from the Updated Health Assessments pilot described in the preamble.</p> <p>This approach will be presented to the EPA's Science and Technology Policy Council (STPC) in June and the SAB CAAC in September 2017 for their consideration and evaluation.</p> <p>In FY 2017, NCEA has also deployed program and project management (PM) for the assessments. These include working with chemical managers to develop timelines and a system that tracks the portfolio of products in development, allowing the IRIS Program to more effectively and efficiently utilize human resources across assessment projects and ensure timely delivery of products. NCEA has developed tools for tracking decisions and actions taken, and has ongoing training for staff and managers in the use of PM tools and systems.</p>
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<p>2. Recommendation: To better ensure the credibility of IRIS assessments by enhancing their timeliness and certainty, the EPA Administrator should require the Office of Research and Development, should different time frames be necessary, to establish a written policy that clearly describes the applicability of the time frames for each type of IRIS assessment and ensures that the time frames are realistic and provide greater predictability to stakeholders.</p>	<p>Status: Open</p> <p>Priority recommendation</p> <p>Comments: In October 2016 we reviewed information provided by EPA related to this recommendation. While in July 2013, EPA issued "enhancements" to the IRIS process and provided us with details on the online information available for each chemical, a written policy that is publicly available is still needed. EPA stated that the Program introduced the idea that different timelines are needed for different types of assessments based on criteria such as complexity (i.e., large database, many endpoints, complex questions about dose-response, multiple science issues, and novel approaches), potential public health impact, and the amount of new research that needs to be considered. Consequently, two sets of timelines for the IRIS assessment process were developed, one set for "standard" assessments and one set for "complex" assessments. GAO believes that EPA has made progress and we will continue to review information provided by EPA as they work to ensure that the time frames are realistic and provide greater predictability to stakeholders.</p> <p>April 2017 Update: After receiving feedback from the EPA SAB CAAC (expected, September 2017), such a public statement will be developed. We expect the statement to emphasize the portfolio approach to chemical evaluation and reflect that the timelines and milestones will be commensurate to the scale and type of assessment product. This will also provide an opportunity to evaluate whether the program and project management training has provided the consistency in planning and delivery that was expected.</p>
<p>4. Recommendation: To ensure that current and accurate information on chemicals that EPA plans to assess through IRIS is available to IRIS users--including stakeholders such as EPA program and regional offices, other federal agencies, and the</p>	<p>Status: Open</p> <p>Comments: In October 2016, EPA provided an update to GAO and said they believe they have met the intent of this GAO recommendation by publishing an IRIS</p>

<p>public--the EPA Administrator should direct the Office of Research and Development to annually publish the IRIS agenda in the Federal Register each fiscal year.</p>	<p>Multi-Year Agenda in December 2015. According to EPA, the Multi-Year Agenda provides detailed information on near-term agency priorities including IRIS assessments that are ongoing and those that will be initiated over the next few years. EPA also told GAO that they are working to update the information provided on the status of each ongoing IRIS assessment. As this important work continues, GAO will monitor EPA's progress and determine if the information provides IRIS users with transparent information about assessments.</p> <p>April 2017 Update: As described in the preamble, starting in 2017, the IRIS Program will ground-truth the information in the Multi-Year Agenda annually to ensure that it remains responsive. An informal process implemented in 2017, will be formalized starting in 2018. Updates to the Agenda will be published on the IRIS website and disseminated appropriately.</p>
<p>5. Recommendation: To ensure that current and accurate information on chemicals that EPA plans to assess through IRIS is available to IRIS users--including stakeholders such as EPA program and regional offices, other federal agencies, and the public--the EPA Administrator should direct the Office of Research and Development to indicate in published IRIS agendas which chemicals EPA is actively assessing and when EPA plans to start assessments of the other listed chemicals.</p>	<p>Status: Open</p> <p>Priority recommendation</p> <p>Comments: In October 2016, EPA provided an update to GAO and said they believe they have met the intent of this GAO recommendation by publishing an IRIS Multi-Year Agenda in December 2015. According to EPA, the Multi-Year Agenda provides detailed information on near-term agency priorities including IRIS assessments that are ongoing and those that will be initiated over the next few years. GAO still believes that annually providing current and accurate information on chemicals that EPA plans to assess through the IRIS program is critical for IRIS users and specifically which chemicals EPA is actively assessing and when EPA plans to start assessments of the other listed chemicals.</p> <p>April 2017 Update: As described in the preamble, starting in 2017, the IRIS Program will ground-truth the information in the Multi-Year Agenda annually to ensure</p>

	<p>that it remains responsive. An informal process implemented in 2017, will be formalized starting in 2018. Updates to the Agenda will be published on the IRIS website and disseminated appropriately. The Program and Project Management tools deployed in FY 2017 are expected to facilitate estimation and adherence to the projected timelines.</p> <p>Following SAB-CAAC evaluation of proposed approaches to ground-truth and update the Multi-Year Agenda (expected, September 2017), an updated agenda will be published that will list which chemicals EPA is actively assessing and when EPA plans to start assessments of the other listed chemicals</p>
<p>6. Recommendation: To ensure that current and accurate information on chemicals that EPA plans to assess through IRIS is available to IRIS users—including stakeholders such as EPA program and regional offices, other federal agencies, and the public—the EPA Administrator should direct the Office of Research and Development to update the IRIS Substance Assessment Tracking System (IRISTrack) to display all current information on the status of assessments of chemicals on the IRIS agenda, including projected and actual start dates, and projected and actual dates for completion of steps in the IRIS process, and keep this information current.</p>	<p>Status: Open</p> <p>Priority recommendation</p> <p>Comments: In October 2016, EPA provided an update to GAO and said they believe they have met the intent of this GAO recommendation by publishing an IRIS Multi-Year Agenda in December 2015. According to EPA, the Multi-Year Agenda provides detailed information on near-term agency priorities including IRIS assessments that are ongoing and those that will be initiated over the next few years. GAO still believes that annually providing current and accurate information on chemicals that EPA plans to assess through the IRIS program is critical for IRIS users. In addition, The Agenda does not identify projected start dates for new assessments, and therefore is not ensuring that current and accurate information on chemicals that EPA plans to assess through IRIS is available to IRIS users.</p> <p>April 2017 Update: Following SAB-CAAC evaluation of proposed approaches to ground-truth and update the Multi-Year Agenda (expected, September 2017), the IRIS website will be updated with this information.</p>

CHEMICAL ASSESSMENTS: An Agencywide Strategy May Help EPA Address Unmet Needs for Integrated Risk Information System Assessments

GAO-13-369: Published: May 10, 2013. Publicly Released: Jun 10, 2013.

Recommendation	Comments
<p>3. Recommendation: To ensure that EPA maximizes its limited resources and addresses the statutory, regulatory, and programmatic needs of EPA program offices and regions when IRIS toxicity assessments are not available, and once demand for the IRIS Program is determined, the EPA Administrator should direct the Deputy Administrator, in coordination with EPA's Science Advisor, to develop an agencywide strategy to address the unmet needs of EPA program offices and regions that includes, at a minimum: (1) coordination across EPA offices and with other federal research agencies to help identify and fill data gaps that preclude the agency from conducting IRIS toxicity assessments, and (2) guidance that describes alternative sources of toxicity information and when it would be appropriate to use them when IRIS values are not available, applicable, or current.</p>	<p>Status: Open</p> <p>Priority recommendation</p> <p>Comments: As of October 2016, EPA indicated that the agency evaluated user needs for toxicity assessments as part of its process for developing the Multi-Year Agenda it issued in December 2015. We will continue to review additional information and documentation on EPA's agencywide strategy to address the unmet needs of EPA program offices and regions, and will update status comments as appropriate.</p> <p>April 2017 Update: As described in the preamble, starting in 2017, NCEA assessments that support policy and regulatory decisions for EPA's programs and regions, and state agencies, are being consolidated into a portfolio of <i>Chemical Evaluation</i> products that optimize the application of best available science and technology. These products are being shaped for use by a diversity of EPA program and regional offices, states, and other Federal agencies. By implementing modernizations to systematic review approaches (for which the new NCEA IRIS Director is a global leader), we expect to significantly increase the throughput of completed assessments.</p> <p>NCEA is also collaborating with EPA's National Center for Computational Toxicology (NCCT) to link the architecture of NCEA's assessment databases (including HERO) with the RapidTox Dashboard being developed by NCCT. This Dashboard is being evaluated through a series of case studies. When developed, the RapidTox Dashboard can be used to inform assessment development and fill gaps in assessments, especially for data poor chemicals. It can</p>

	<p>also incorporate diverse data streams, including data from non-animal testing strategies, to develop diverse products for chemicals that are in need of assessments.</p> <p>In June 2017, NCEA will present these advances to EPA's Science Technology and Policy Council (STPC), in the Office of the Science Advisor.</p>
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Validation Strategy: In Spring/Summer 2017, in coordination with GAO, ORD is developing a strategy to address the remaining open GAO recommendations, with a goal of closing all remaining open recommendations by Summer, 2018. Fiscal year 2017 is a critical year to focus on closing the remaining recommendation from the 2013 GAO report, pertaining to an agency-wide strategy to address program and regional office needs when IRIS assessments are not available. ORD plans to coordinate with GAO to evaluate the effectiveness of the strategy and incremental progress to address the remaining recommendations.

3. **Status of Related Audits:** In the FY 2017 annual plan, OIG indicates they are planning an evaluation of the IRIS Program, beginning in March of 2017. The report states that the purpose of the evaluation is to “Determine what internal controls the Integrated Risk Information System program, within the Office of Research and Development, currently has in place; and whether the existing controls ensure the effective operation of the program.”
4. **Responsible Manager:**

Christopher S. Robbins
Acting Deputy Assistant Administrator for Management/ORD

Date